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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,898	08/22/2003	Joar Opheim	012098-0012-999/NN009	1343

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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02/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,898	OPHEIM, JOAR	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 2, 5, 8, 17, 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 5, 8, 17, 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 10/13/2009.

Claims 1-9, and 14-16 previously presented.

Claims 3, 4, 6, 7, 9-16 have been canceled, and claims 17and 18 are currently added.

Claims 1, 2, 5, 8, 17 and 18 are pending and included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 8, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lachman et al. in combination with the article "Encyclopedia of Pharmaceutical Technology", provided by applicant in the IDS filed 01/21/2009, US 5,955,102 ('102), and US 5,817,323 ('323).

Lachman teaches a capsule shell comprising gelatin, plasticizer, water and flavor. The amount of plasticizer is calculated to be 40-60% and chosen according to the end use of the capsule and the effect of capsulated material on the shell. The amount of water is calculated to be 70-130% but water is lost during drying process. The flavor is present in a concentration of 0.1% to impart the desirable taste in chewable capsule (page 407, right column).

Lachman does not teach the claimed amount of the water and plasticizer, or fish oil as a dietary supplement.

However, Lachman suggested that plasticizer is chosen according to the end use of the capsule and the effect of capsulated material on the shell, and this teaching would have motivated one having ordinary skill in the art to adjust the amount of plasticizer according to the intended use and encapsulated material.

Additionally, Lachman teaches that the water is lost during drying process, i.e. the amount is expected to be radically reduced below 70%. Note that applicant discloses in page 6 of the specification, lines 1-2, that the amount of water present in the shell is 10-45%, and that amount is reduced to 8+/-2% after drying of the capsule.

The article "Encyclopedia of Pharmaceutical technology" teaches that the flavor can be included in the shell in small amount (page 287). The article further teaches that the shell contain 5-10% water after drying and teaches that increasing the water content results in making the capsules more soft and stick together and may leak affecting potency of the capsule (pages 276-279).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide soft gelatin capsule coated with flavored shell containing gelatin, plasticizer, flavor and water as disclosed by Lachman and adjust the amount of water to between 5-10% as disclosed by the article "Encyclopedia of Pharmaceutical technology". One would have been motivated to do so because "Encyclopedia of Pharmaceutical Technology" teaches that decreasing the water content in the shell to between 5-10% water and teaches that higher water content results in making the capsules more soft and sticking together and may leak affecting potency of the capsule. One would have reasonably expected formulating soft gelatin capsules having flavored shell containing 5-10% water wherein the capsules are not sticking together nor leaking and have extended potency.

Fish oil is well known dietary supplement, and also known to be provided in a gelatin capsules combined with flavoring agents.

US '102 teaches fish oil is preferably provided in a gelatin capsule (abstract; col.2, lines 31-36).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide shell of gelatin capsule as disclosed by Lachman that comprises gelatin, softener, 5-10% water and small amount of flavor as disclosed by the combination of Lachman and the article "Encyclopedia of Pharmaceutical Technology", and use the capsule to deliver fish oil as disclosed by US '102. One would have been motivated to do so because US '102 teaches that the gelatin capsules are the preferred delivery method for the fish oil. One would have been

reasonably expected formulating a gelatin capsule filled with fish oil and having shell containing gelatin, softener, 5-10% water and small amount of flavoring agent to successfully provide fish oil in pleasant form to the patient in need of such a nutrient.

The combination of Lachman, the article "Encyclopedia of Pharmaceutical Technology" and US '102 does not explicitly teach water-soluble fruit flavors.

US '323 teaches soft gelatin capsule shell comprising flavoring agent selected from essential oils and fruit flavor or combinations thereof (col.5, lines 43-49). Examples C9 and C10 showed lemon flavor, as instantly claimed. Fruit flavors are expected to be water-soluble since compounds and their properties are inseparable.

Therefore, the prior art recognized gelatin capsules with flavored shell, and also recognized the equivalency as well as the combination of essential oil flavors and fruit flavors.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide gelatin capsule to deliver fish oil comprising shell containing 1% of flavoring agent and 5-10% water to impart the desired taste as disclosed by the combined teaching of Lachman, "Encyclopedia of Pharmaceutical Technology" and US '102, and further add fruit flavor or replace the essential oil with the fruit flavor, especially lemon flavor, as disclosed by US '323. One would have been motivated to do so because US '323 desired to add essential oil or fruit flavors, or their combination, to the shell of gelatin capsule, and because US '323 further preferred and exemplified lemon flavor. One would have reasonably expected formulating gelatin capsule to deliver fish oil comprising shell containing 1% of fruit flavor and specially

lemon flavor, and 5-10% water, to impart palatable taste to unpleasant fish oil content of the capsule to successfully improve patient compliance.

Regarding claims 8 and 9, it is known in the art to flavor the contents of the gelatin capsule as disclosed by the article "Encyclopedia Pharmaceutical Technology" and by US '323, and one having ordinary skill in the art at the time of the invention would have flavored the oily material encapsulated in the gelatin capsule with oily flavor to ensure its solubility in the capsule contents.

Response to Arguments

3. Applicant's arguments filed 10/13/2009 have been fully considered but they are not persuasive.

Applicant argue that Applicant's showing of commercial success and the satisfaction of a long-felt need in the Declarations of Joar Opheim dated September 21, 2006 and January 16, 2009 and the Declaration of Oliver Cooperman, dated March 29, 2007, is sufficient to rebut any conclusion of obviousness with respect to the presently claimed subject matter. In particular, the claims are presently drawn to a flavored capsule encapsulating a dose of fish oil, wherein the capsule comprises inter alia about 1.5% water soluble lemon flavoring. Applicant respectfully submits that the Opheim Declaration dated January 16, 2009 establishes that the embodiments of the invention which achieved commercial success and satisfied a long-felt need were flavored capsules encapsulating a dose of fish oil, wherein the capsule comprises inter alia about 1.5% water soluble lemon flavoring. Accordingly, Applicant's evidence of

commercial success and satisfaction of a long-felt need correspond exactly in scope to the present claims and therefore suffice to rebut any conclusion of obviousness.

In response, it is notices that the objective evidences are insufficient to overcome the rejection of the claims based upon U.S.C. 103 (a) as set forth in the last Office action because: there was no showing that the objective evidence of nonobviousness as well as commercial success are commensurate in scope with the claims. See MPEP § 716. The scope of the claims is broad covering all flavors in amounts of 1.5%, while the declaration is limited only to one flavor, lemon flavor, at specific concentration of 1.0% in the shell and 1.0% in the content of the capsule, even it mention range from 0.25-1.5%, but no showing of unexpected results of range as low as 0.25% or as high as 1.5%. No showing of effect of range below claimed amount or over the claimed amount to establish superiority of the results. There is no comparative data between the claimed amount of the flavor with amounts outside the claimed amount. Objective evidence of nonobviousness must be commensurate in scope with claims that evidence is offered to support. See in *Greenfield and DuPont* 197 USPQ 227 (CCPA 1978); *In re Boesch and Slaney* 205 USPQ 215 (CCPA 1980); and *In re Tiffin and Erdman* 170 USPQ 88 (CCP 1971).

The declarations include statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

Further, the present invention is taught by the combination of the cited prior art. Gelatin capsules to administer fish oils is known, flavored shell was known, specific flavors and small amounts of flavor in the shell all were known at the time of the invention.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00

PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611